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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/524,422	03/11/2000	Randall W. Nelson	41821.0236	6081

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EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 01/05/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/524,422

Applicant(s)

NELSON, RANDALL W.

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 4 and 9-22 is/are pending in the application.
- 4a) Of the above claim(s) 9-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3 and 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the claims

The Request for Continued Examination, amendment and declaration filed October 27, 2003 is acknowledged and has been entered.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1, 3 and 4 are rejected under 35 U.S.C. 102(a) as being anticipated by Nelson et al (Mass Spectrometric Immunoassay, Anal. Chem. 1995, 67, 1153-1158).

Nelson et al disclose a filter pipette tip having an affinity reagent (beads containing immobilized antibodies) present within the tip (p. 1154 experimental section, see also figure 1).

3. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Ollington et al (US 5,403,745).

Ollington et al disclose a pipette comprising antibodies immobilized to beads (solid substrate). Ollington et al disclose that a modified pipette tip can contain a filter within the pipette tip (col 13, lines 41-43 and figures 13-15).

4. Claims 1, 3 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Rampal et al (US 5,437,979).

Rampal et al disclose a pipette tip that is modified or adapted to hold a solid phase support in a secure manner while still permitting the free flow of fluids into and out of the pipette tip. Rampal et al disclose that this can be done with porous frits (filter) (col 2, lines 8-18). Rampal et al disclose that the solid phase support comprise immobilized species (analytes).

Response to Arguments

Applicant argues that the declaration filed October 27, 2003 and signed by Randall W. Nelson, an inventor in the instant application and the principal investigator involved in the printed publication entitled "Mass Spectrometric Immunoassay", anal. Chem. 1995, 67, 1153-1158 listing Randall W. Nelson, Jennifer R. Krone, Allan L. Bieber, and Peter Williams as authors. Applicant relies on the declaration filed October 27, 2003 to overcome the Nelson et al reference. This declaration is not found

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persuasive because section 1 of the declaration submitted by Randall W. Nelson states "I am a co-inventor in application having Serial No. 09/524,422 along with Peter Williams and Jennifer Reeve Krone". This declaration contradicts the originally filed declaration submitted March 11, 2000, which lists only Randall W. Nelson as the inventor. Jennifer Reeve Krone and Peter Williams are not listed as inventors of the present application (09/524,422). Therefore, the 102 rejection concerning the Nelson et al reference is maintained.

Applicant argues that Ollington et al (US 5,403,745) fails to disclose each and every element of Applicants' claimed invention, namely at least an antibody or antigen immobilized to a solid substrate to form an affinity reagent and a pipette tip having a filter element contained therein for retaining the affinity reagent. Applicant specifically states that the filter element is clearly not contained within the pipette tip. This is not found persuasive because Ollington et al specifically teaches that the pipette tip can be a modified pipette tip having the filter element contained within the pipette tip (Fig. 15).

Conclusion

5. No claims are allowed.
6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Guirguis (US 5,042,502) disclose an apparatus and method, which can use immunoassay in sample treatment (see whole document).

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Good et al (US 5,595,653) disclose an apparatus for extracting an analyte from a liquid sample, comprising a microcolumn having a microparticulate media therein, the media being sandwiched between two compression layers.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gary W. Counts
Examiner
Art Unit 1641
December 29, 2003



MARY E. CEPERLEY
PRIMARY EXAMINER
AU 1641